



## NATIONAL PHARMACEUTICAL ALLIANCE

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Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

March 27, 1999

**Docket No. 98D-1266**

Gentlemen:

Enclosed are two copies of comments on the draft document "Guidance for Industry; Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling" which closes March 29, 1999. These comments are made by the Technical Committee of the National Pharmaceutical Alliance.

Very truly yours,

*Robert A. Sizemore*

Chris Sizemore  
President

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An Alliance of Manufacturers and Distributors of Pharmaceuticals

Comments from the NPA's Technical Committee on the GUIDANCE FOR INDUSTRY;  
Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.

March 27, 1999

The availability of this guidance was published in the Federal Register on January 28, 1999, Vol. 64, No. 18, p 4434-4435, Docket Number 98D-1266. The guidance advises applicants, repackers, and distributors of the preferred format and placement of the therapeutic code on drug product labels.

The National Pharmaceutical Alliance agrees with the draft guidance and the Agency's attempt to reduce the chances when multiple reference listed products exist with the same established name and strengths that a generic drug product will be dispensed to a patient that is not therapeutically equivalent to the one intended or previously prescribed.

We have a few comments on the guidance:

1. With regard to displaying the therapeutic equivalence code on container and carton labeling, we recommended that the word "rated" appear after the code designation. Thus, instead of "AB to Drug Name", we recommend "AB rated to Drug Name".
2. The guidance states that the applicant, repacker, or distributor is responsible for ensuring that the therapeutic equivalence code in labeling is accurate and current in accord with the Orange Book. The guidance also states that an inaccurate statement in the labeling regarding the therapeutic equivalency could deem the product as misbranded and result in the product being subject to regulatory action. We recommend that the latter be reserved for a firm who has a pattern of placing inaccurate codes in the labeling rather than for a firm which makes a simple error on one drug or is slow to change the code after a change appears in the Orange Book.
3. We agree that this program should be voluntary and that the changes may be made via annual reports.